DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 31 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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85 India Row, Apartment 25F
Boston, MA 02110

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PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 00N-1526

Dear Dr. Fiddes:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debarring you for a period of 20 years from providing services in any capacity to a person that has an approved or pending drug product application. The FDA bases this proposal on a finding that: (1) you were convicted of one count of conspiring to make false statements to a government agency, a Federal felony offense under 18 U.S.C. sections 371 and 1001; and (2) you were a material participant in offenses for which three other people are being debarred. This letter also offers you an opportunity for a hearing on the proposal.

Conduct Related to Debarment

On September 30, 1997, the United States District Court for the Central District of California accepted your plea of guilty and entered judgment against you for one count of conspiring to make false statements to a government agency, in violation of 18 U.S.C. sections 371 and 1001. The underlying facts supporting this felony conviction are as follows:

You were owner and president of American Pharmaceutical Research, Inc., formerly known as Southern California Research Institute (collectively SCRI), a private company retained by drug manufacturers to conduct clinical studies of new pharmaceutical products.

You were the principal investigator at SCRI and participated in numerous clinical studies conducted under investigational new drug applications (INDs) for numerous products, including Clotrimazole for the treatment of vaginal candidiasis, Sparfloxacin for the treatment of sinusitis, PHZ-136 for arthritis, and Salmeterol for the treatment of asthma. As an investigator, you were required by FDA regulations to conduct the studies in accordance with protocols

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contained in the INDs. You were required to, among other things, enroll in the study subjects meeting criteria specified in the protocols, administer the study drugs, meet regularly with subjects, and maintain adequate and accurate record case histories and other pertinent data collected during the study.

Beginning on a date unknown and continuing through at least December 1, 1996, you and various study coordinators at SCRI routinely falsified data on the studies. You admitted, among other things, that you and your staff, with your knowledge, approval, or under your direction: falsely reported that certain subjects participated in clinical trials when, in fact, they had not; substituted samples and data from qualifying subjects for nonqualifying subjects; destroyed x-ray films showing that certain subjects enrolled in clinical studies did not meet the inclusion criteria; falsified Holter monitor data for certain subjects; enrolled nonexistent and nonqualifying subjects in the clinical studies and falsified data for those nonexistent and nonqualifying subjects. Upon completion of the studies, you submitted the results of the studies to the drug sponsors who, in turn, submitted the results to FDA in support of their new drug applications for their drug products.

On September 30, 1997, you agreed to waive indictment and to plead guilty to a criminal information charging you with one count of conspiring to make false statements to a Federal agency in violation of 18 U.S.C. sections 371 and 1001. On September 15, 1998, the United States District Court for the Central District of California sentenced you for this offense.

In addition to your conviction, you were a material participant in acts for which three other SCRI employees, Laverne Charpentier, Delfina Hernandez, and Elaine Lai, were convicted and for which they are being debarred under section 306(b)(2)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the Act). You were aware of these acts by SCRI employees, yet took no remedial action.

FDA's Finding

Section 306(b)(2)(B)(i)(II) of the Act (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits the FDA to debar an individual if it finds that the individual has been convicted of a felony under Federal law for conspiracy to commit a criminal offense relating to the development or approval, including the process for the development or approval, of any drug product, or otherwise relating to the regulation of drug products under the Act, and that the offense undermines the process for the regulation of drugs. Your felony conviction under 18 U.S.C. sections 371 and 1001 was for conspiring to defraud FDA by falsifying important data for studies used by the Agency to determine whether new drugs should be approved, an offense relating to the development or approval of any drug product. This conduct undermines the process for regulation of drugs. Accordingly, the Agency finds that you are eligible for permissive debarment.

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Section 306(b)(2)(B)(iii) of the Act (21 U.S.C. 335a(b)(2)(B)(iii)) permits the FDA to debar an individual who materially participated in acts that were the basis for a conviction of another person for an offense under section 306(a) or section 306(b)(2)(B)(i) or (ii) of the Act, if FDA finds that the individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under the Act relating to drug products.

Your conviction for conspiracy to commit a criminal offense is based, in part, on evidence of illegal conduct by you, Laverne Charpentier, Delfina Hernandez, and Elaine Lai, showing that you directed and encouraged the actions that were the basis for their felony convictions relating to the development or approval of drug products. The Agency is in the process of debarring Laverne Charpentier, Delfina Hernandez, and Elaine Lai under section 306(b)(2)(B)(i)(II) of the Act. Your actions as a material participant in the acts leading to the conviction of Ms. Charpentier, Ms. Hernandez, and Ms. Lai and upon which your own conviction is based demonstrate a pattern of conduct sufficient to find that there is reason to believe you may violate requirements relating to drug products again.

Under section 306(l)(2) of the Act, permissive debarment may be applied when an individual is convicted within the 5 years preceding this notice. You were convicted on September 30, 1997, less than 5 years ago. The Agency may debar you for up to 5 years for each offense, and can determine whether the debarment period for multiple offenses shall run concurrently or consecutively (306(c)(2)(A) of the Act) (21 U.S.C. 335a(c)(2)(A)). A person debarred for multiple offenses means a person debarred for two or more offenses described in section 306(a) or (b)(2).

FDA finds that you have committed one offense and participated in three other offenses for which you may be permissively debarred: (1) under section 306(b)(2)(B)(i)(II), you are eligible because you were convicted of conspiracy to commit a crime relating to the development or approval of drug products; (2) under section 306(b)(2)(B)(iii), you are eligible because of your involvement as a material participant in Ms. Charpentier's offense, as described above; (3) under section 306(b)(2)(B)(iii), you are eligible because of your involvement as a material participant in Ms. Hernandez' offense, as described above; and (4) under section 306(b)(2)(B)(iii), you are eligible because of your involvement as a material participant in Ms. Lai's offense, as described above. All three individuals have been convicted of individual offenses.

Section 306(c)(3) of the Act provides six factors for consideration in determining the appropriateness of and the period of permissive debarment for a person (21 U.S.C. 335a(c)(3)). These are as follows:

(A) the nature and seriousness of any offense involved,

(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

(F) prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

The Agency considers that four of these factors are applicable for consideration:

1. The nature and seriousness of the offense involved (Factor A)

You were convicted of one count of conspiring to make false statements to a government agency, the FDA, based on your submission of false information to sponsors in required reports for clinical studies used by FDA to evaluate the safety and effectiveness of drug products. Your illegal conduct involved numerous drug products indicated for a variety of conditions.

The Agency finds that your conduct undermined the integrity of the drug approval and regulatory process because FDA's regulatory decision on whether or not to grant or withhold approval of the drugs was based on information that you falsified on the studies and submitted to the drug sponsors in required reports. Accordingly, the Agency will consider the nature and seriousness of the conduct underlying your conviction as an unfavorable factor.

Furthermore, some of the drugs for which you submitted false data, for example, Dilacor and Salmeterol, are indicated for serious or life-threatening conditions. Dilacor is indicated for the treatment of hypertension and for the management of chronic stable angina. Salmeterol is indicated for the maintenance treatment of asthma and in the prevention of bronchospasm (*2002*

Physicians Desk Reference). Accordingly, the Agency will consider your conduct an extremely unfavorable factor because your actions potentially undermined the safety or effectiveness of drugs used for life-threatening or serious conditions.

2. The nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense (Factor B)

You participated in the planning of, directed, and initiated the conduct underlying your conviction. You were the principal investigator for all drug research conducted at SCRI. You admitted that you, as well as certain study coordinators at SCRI, under your direction or with your knowledge and approval, routinely and deliberately failed to conduct clinical studies in accordance with study protocols, fabricated data on the studies to conceal such illegal conduct, and submitted the fraudulent data to sponsors of the drugs in required reports. Therefore, the Agency considers the nature and extent of your participation as an unfavorable factor.

3. The nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health (Factor C)

You received financial gain in exchange for the conduct underlying your conviction. SCRI was hired by a number of drug manufacturers to conduct IND studies in human subjects for numerous drug products. As owner and clinical investigator of SCRI you profited from the financial compensation paid to SCRI for conducting the studies.

You did not report drug-related violations nor did you take action to correct the violations, although you knew the actions were violative of the law. In your capacity as a clinical investigator, you were required to follow certain procedures set forth in the Act and regulations. You admitted that you were aware of these requirements. However, you repeatedly and deliberately deviated from such regulatory procedures in conducting the studies. Specifically, the violations committed by you and various SCRI study coordinators with your knowledge and under your direction, included, among other things: enrolling nonexistent subjects in a study on Dilacor and falsifying Holter monitor data relating to heart rhythm measurements for certain subjects who did not participate in the study; enrolling otherwise nonqualifying subjects into drug studies by falsifying subjects' electrocardiogram results and by substituting the subjects' blood with the blood of study coordinators at SCRI; using microorganisms purchased from

outside laboratories to qualify otherwise nonqualifying subjects in a study on Azithromycin; using exclusionary medication to control subject bleeding in a study on a drug product known as Combi-Patch; destroying x-ray film reports showing that certain subjects enrolled in a study on the drug product known as PHZ-136 did not have osteoarthritis of the knee as required by the study protocol; falsifying study documentation to make it appear that more than 25 subjects participated in a study on Clotrimazole when only one subject participated in the study; substituting urine with required protein levels for urine of otherwise ineligible subjects so those subjects could be enrolled in the study on Eprosartan 090; allowing study coordinators to use personal information on themselves and their family members to indicate that they were participating in studies on a drug product known as Salmeterol and a drug product known as Triphasic Pill. You submitted the fraudulent study data to the drug manufacturers, knowing that such fraudulent data would be submitted to FDA in support of approval of new drug applications to market the drugs.

Your actions reveal that you were not concerned with the drug regulatory process or the welfare of the subjects who participated in the studies or of the public at large. The Agency finds that you displayed a wanton disregard for the public health and the drug regulatory process. Accordingly, the Agency will consider the nature and extent of mitigation as an extremely unfavorable factor.

4. Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration (Factor F)

The Agency is unaware of any prior convictions.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, the FDA proposes to issue an order under section 306(b)(2)(B) of the Act, debarring you from providing services in any capacity to a person having an approved or pending drug product application for 4 periods of 5 years, to run consecutively. You were convicted of one count of conspiracy to make false statements to a government agency, a felony described in section 306(b)(2)(B)(i)(II) and (a)(2), and you were a material participant, who qualifies for debarment under section 306(b)(2)(B)(iii), in the offenses leading to the conviction and debarment of three other SCRI employees. The Agency proposes a 5-year debarment period for each offense, based on the factors discussed above.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given notice of an opportunity for a hearing to show why you should not be debarred as proposed in this letter. If you decide to seek a hearing, you must file: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing, and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The

procedures and requirements governing formal evidentiary hearings as applied to debarments are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes a waiver of your right to a hearing. If you do not request a hearing in the manner prescribed by the regulations, the Agency will not hold a hearing and will issue a final debarment order as proposed in this letter.

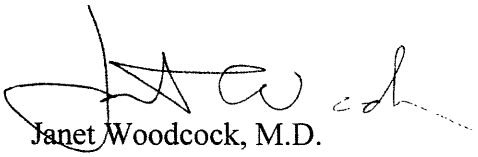
A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether this conviction and your actions as a material participant subject you to debarment under section 306(b)(2)(B) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 00N-1526 and sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. You must file four copies of all submissions under this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 306 (21 U.S.C. 335a)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.99).

Sincerely yours,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research